

MTN-017

Participant Selection

HIV/STD Research Program
Thailand MOPH – US CDC Collaboration
Bangkok, Thailand

6 June 2013

Silom Community Clinic Research Team

- High retention in Bangkok MSM Cohort Study over 3-5 years
- High retention in Bangkok Tenofovir Study Trial over 8 years
- Perfect (100%) retention in HPTN-067 after 1 year
- Our CRS considers finding the optimal participants to maximize retention very important



What does the 'optimal' MTN-017 participant look like to us?

- Desire to want to help others/ Buddhist “merit making”
- Motivated and interested to participate in research
- History of visiting SCC for cohort study or VCT (monthly and sometimes weekly) frequently
- Self aware about perineal area, has history of having anal exam or at least not squeamish, comfortable with their own anal health
- Comfortable about applicators, and/or has familiarity with rectal douching
- Minimal frequency of receptive sex (planned to have ~1-3 times a month)
- Almost always uses (receptive) condom/lube
- Comfortable with medical procedures/sigmoidoscope

How are we pre-screening participants?

- **Educational tools**

- Timetable tool – one page of visit frequency, potential time requirements, number of visits, length of visits, randomization and crossover
- Pictures of equipment (sigmoidoscope, applicator, pills)

- **Checklists**

- ACASI screening questions (condom use, frequency of visit, previous STI, rectal douching)
- Identification of potential barriers to availability and participation with visits and schedule (working hours, distance to living location, transport restrictions)

- **Nurse interview**

- Silom Clinic nurses get to know participants quite well, understand their personality, motivation, “what makes them tick”

Recruitment lessons learned from previous studies

Describe lessons learned from recruiting for other PrEP or microbicide studies

- Frequency of study visits – HPTN-067
- Participants have been concerned about how often they must come, but so far every enrolled participant has attended 100% of the time (100% retention)
- Participants have done their best despite rigorous schedule
- Side effects
 - We instruct participants that they can come back anytime, that AE's are minimal if at all, we always dispense with caution
 - Truvada® is among the most safe HIV/AIDS drugs in use
 - Close supervision and monitoring of AE's in the population, “we are ready to assist you about any concerns”
- Resistance risk
 - So far seen only in those who do not take as prescribed

Where and how will our efforts be focused?

For each item below, describe how your site will focus its efforts on enhancing the involvement of each of the groups below.

- Site Leadership

- Engaged in all aspects of the trial

- Clinical Staff

- Be truthful and forthright with potential participants
- Experience, low turnover rate, commitment

- Counseling staff

- Refresher training course three times/year

- Community Outreach team

- Engage with CAB and HPTN CWG
- Using chat application [Line, Twitter, or Facebook] to educate or prep them about the study
- Use participants as word-of-mouth recruiters (this has worked quite well for cohort study recruitment)

Summary

- High interest in finding motivated, self aware, enthusiastic study participants
- Nurses have 7 years of experience working with the study population, are very “tuned in” to what needs and interests are, will enhance with educational tools and checklists
- Lessons learned from HPTN-067 about study visit frequency and concerns about side effects will be applied
- Finding the optimal participants is a team effort